II. PROCEDURES FOR OBTAINING REVIEW BY THE INSTITUTIONAL REVIEW BOARD (IRB) OF THE VIRGINIA DEPARTMENT OF HEALTH (VDH)

A. Introduction

Researchers and managers who have reviewed the guidelines and have made the determination that a project does indeed involve human subjects and is considered research will need to make a request for IRB review. Requests for IRB review will fall into one of three categories:

(1) Request for Full Board Review;
(2) Request for Expedited Review; or
(3) Request for Exemption from IRB Review.

All requests for review are to be submitted to the Office of Minority Health and Public Health Policy /Institutional Review Board, VDH. Criteria and procedures for obtaining clearance for each of the specific categories are described in Sections B, C, and D.

1. **General Criteria for IRB Approval of Research:** In order to approve non-exempt research, the IRB will consider the following elements of the proposal:

   a. The adequacy of the description of the potential benefits and risks involved and the adequacy of the methodology of the research. *Risks to subjects are to be minimized and benefits to subjects maximized by using procedures which are consistent with sound research design*

   b. The degree of risk, and, if the research is nontherapeutic*, whether it presents greater than minimal risk****.** *Risks to subjects are to be minimized by using procedures which do not unnecessarily expose the subjects to risk, and whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.*

   c. The necessity and utility of the research and whether the risks to the subjects are outweighed by the potential benefits of the research and the importance of the knowledge that may reasonably be expected to result. *In evaluating risks and benefits, the IRB will consider only risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB will not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks or potential benefits that fall within the purview of its responsibilities.*

   d. The equity in criteria for selection of subjects, especially in research regarding the future development of mental or physical illness**.** *In making this assessment, the IRB will take into*

** "Nontherapeutic research" means human research in which there is no reasonable expectation of direct benefit to the physical or mental condition of the participant.*

*** Minimal risk" means that the risks of harm or discomfort anticipated in the proposed research are not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.*

account the purposes of the research and the setting in which the research will be conducted and will be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically/educationally disadvantaged persons.

e. The adequacy of protection of rights and welfare of the participants. These include the following:

- *Voluntary informed consent is sought from each prospective subject or the subjects' legally authorized representative and appropriately documented.*
- *Voluntary informed consent is obtained by methods that are adequate and appropriate to the subject's educational level and language of greatest fluency.*
- *The written consent form is adequate and appropriate in both content and wording for the particular research and for the particular subjects of the research relative to their educational level and language of greatest fluency and reasonably reflects full explanation and adequate understanding.*
- *The person(s) proposed to supervise or conduct the particular research protocol are appropriately competent and qualified.*
- *When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.*
- *When appropriate, there are adequate provisions to protect the privacy of the subjects and to maintain the confidentiality of data.*
- *When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically/ educationally disadvantaged persons, additional safeguards are included in the study to protect the rights and welfare of these subjects*

2. General Requirements for Informed Consent: Informed consent means the knowing and voluntary agreement, without undue inducement or any element of force, fraud, deceit, duress, or other form of constraint or coercion, of a person who is capable of exercising free power of choice. For the purposes of human research, the basic elements of information necessary to be given before such consent can be attained shall include:

a. a statement that the study involves research; an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures or protocols to be followed, identification of any procedures which are experimental; and where applicable, disclosure of the approximate number of subjects involved in the study;

b. a description of any reasonably foreseeable risks or discomforts to the subject and a statement that there may be other risks not yet identified (e.g.; a statement that the particular treatment or procedure may involve risks to the subject or to the embryo or fetus, if the subject is or may become pregnant, which are currently unforeseeable);

c. a description of any benefits to the subject or to others which may reasonably be expected from the research; and a statement that significant new findings developed during the course of the research which may be related to the subject's willingness to continue participation will be provided to the subject;

d. a disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

e. a statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained; and if any data from the study are published, a statement that the subject will not be identified without the subjects written permission;

f. for research involving more than minimal risk*, an explanation as to whether any compensation or medical care is available if injury occurs and, if so, what is included or where further information may be obtained;

g. an explanation of any costs or compensation which may accrue to the subject and, if applicable, the availability of third party reimbursement for the proposed procedures or protocols;

h. an offer to answer any inquiries by the subject concerning the procedures and protocols, and an explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject;

i. a statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may withdraw his consent and discontinue participation at any time without prejudice;

j. where applicable, a disclosure of the consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject; and

k. where applicable, any anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.

The IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent provided the IRB finds and documents that:

a. the research involves no more than minimal risk* to the subjects;

b. the waiver or alteration will not adversely affect the rights and welfare of the subjects;

* "Minimal risk" means that the risks of harm or discomfort anticipated in the proposed research are not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

c. the research could not practicably be carried out without the waiver or alteration; and

d. whenever appropriate, the subjects will be provided with additional pertinent information after participation

3. **General Requirements for Documentation of Informed Consent:** Informed consent shall be documented by the use of a written consent form approved by the IRB (a sample consent form is in Appendix C) and signed by the subject or the subject's legally authorized representative with the exception of the following situations:

   a. that the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or

   b. that the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

   In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

   The consent form may be either a written form that embodies the elements of informed consent or a short-form written document stating that the elements of informed consent have been presented orally to the subject or the subject's legally authorized representative and witnessed by a third party. In either case, a copy of the document shall be given to the person signing the form. If oral presentation is being proposed, a written summary of the oral presentation in addition to the short-form written document should be included in the documentation portion of the request for review being made to the IRB.

All forms and documents should be submitted to:
Office of Minority Health and Public Health Policy/
Institutional Review Board
Virginia Department of Health
109 Governor Street, 10th Floor East
P.O. Box 2448
Richmond, VA 23218-2448

For questions or additional information, please contact:
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B. Requests for Full Board Review

The following is a checklist of documents that must be submitted by the principal investigator in order to obtain full board review and clearance:

- ❑ Request for Review and Clearance of a Project Involving Human Subjects (Appendix D) with requested supporting documentation to include the study protocol (if the study is a part of a larger protocol, such as a cooperative agreement with CDC for public health surveillance/intervention, only submit relevant portions of the protocol) and informed consent form(s). Study protocols should include sections on Hypotheses, Goals of Study, Background and Significance of Study, Preliminary Progress/Data Report (if available), Research Method and Design, and Statistical Analyses Planned (or in progress).

- ❑ Letter(s) and other materials that will be supplied to study subjects

- ❑ Questionnaire(s) (when applicable)

Full Board review requires the submission of 1 electronic OR 7 hard copies of the "Request for Review" application and supporting documents, and requires attendance of the principal investigator at a meeting of the IRB. The IRB is required by state regulations to review all requests within 45 days after submission. The IRB is scheduled to meet quarterly (January, April, July, October) and will convene more often as needed. In order for research to be approved, it must receive the approval of a majority of those members present at a meeting in which a quorum exists. A quorum consists of a majority of the members, including at least one member whose primary concerns are in a nonscientific area. All IRB decisions regarding approval, disapproval, or of required modifications will be communicated to the investigator in writing within 7 business days of the IRB meeting where the submission is reviewed.

Continuation Review reports are to be submitted at least annually for all approved studies to ensure conformity with the proposal. The frequency of such reports shall be consistent with the nature and degree of risk of each research project. In addition, the IRB will require a study summary report from the investigator at the conclusion of the research project. The Office of Minority Health and Public Health Policy/Institutional Review Board will automatically mail out the continuing review report form (Appendix E) to principal investigators just prior to the review due date. The form must be completed and returned for ongoing projects.

Finally, whenever an ongoing project acquires a new principal investigator, or whenever there are substantial changes (e.g., changes in consent procedures, addition of potentially sensitive items to research instruments, changes in treatment procedures) in the protocol or the subject population, another request for IRB review must be filed.

C. Requests for Expedited Review

The following is a checklist of documents that must be submitted by the principal investigator in order to obtain expedited IRB review and clearance:

- ❑ Request for Review and Clearance of a Project Involving Human Subjects (Appendix D) with requested supporting documentation to include the study protocol (if the study is a part of a larger protocol, such as a cooperative agreement with CDC for public health surveillance/intervention, only submit relevant portions of the protocol) and informed consent form(s). Study protocols should include sections on Hypotheses, Goals of Study, Background and Significance of Study, Preliminary Progress/Data Report (if available), Research Method and Design, and Statistical Analyses Planned (or in progress).

- ❑ Letter(s) and other materials that will be supplied to study subjects

- ❑ Questionnaire(s) (when applicable)

- ❑ CV or resume of Principle Investigator

- ❑ IRB approval document(s) (if requesting expedited review because the study has been approved via Full Board Review by the IRB at another institution or agency)

Expedited review requires the submission of 1 electronic OR 2 hard copies of the "Request for Review" application and supporting documents. The decision to approve or disapprove a project submitted for expedited review will be made by the Chair of the IRB or his/her designee and one additional member of the review board. All IRB decisions regarding approval, disapproval, or of required modifications will be communicated to the principal investigator in writing within 15 business days following submission.

Continuation Review reports are to be submitted at least annually for all approved studies to ensure conformity with the proposal. The frequency of such reports shall be consistent with the nature and degree of risk of each research project. In addition, the IRB will require a study summary report from the investigator at the conclusion of the research project. The Office of Minority Health and Public Health Policy/Institutional Review Board will automatically mail out the continuing review report form (Appendix E) to principal investigators just prior to the review due date. The form must be completed and returned for ongoing projects.

Finally, whenever an ongoing project acquires a new principal investigator, or whenever there are substantial changes (e.g., changes in consent procedures, addition of potentially sensitive items to research instruments, changes in treatment procedures) in the protocol or the subject population, another request for IRB review must be filed.

D. Requests for Exemption from IRB Review

If an investigator believes that their research project qualifies for exemption (see Step 3), the following is a checklist of documents that must be submitted in order to obtain IRB exemption status:

- ❑ Request for Exemption from IRB Review Form (Appendix F)
- ❑ Cover letter with a detailed written explanation of why the project should be regarded as exempt
- ❑ Study protocol (if the study is a part of a larger protocol, such as a cooperative agreement with CDC for public health surveillance/intervention, only submit relevant portions of the protocol). Study protocols should include sections on Hypotheses, Goals of Study, Background and Significance of Study, Preliminary Progress/Data Report (if available), Research Method and Design, and Statistical Analyses Planned (or in progress).
- ❑ Letter(s) and other materials that will be supplied to study subjects
- ❑ Questionnaire(s) (when applicable)
- ❑ CV or resume of Principal Investigator

Exemption review requires the submission of 1 electronic OR 2 hard copies of the "Request for Exemption" application and supporting documents. The decision to approve or disapprove a project submitted for exemption review will be made by the Chair of the IRB or his/her designee and one additional member of the review board. All IRB decisions regarding approval, disapproval, or of required modifications will be communicated to the principal investigator in writing within 15 business days following submission.

All forms and documents should be submitted to:
Office of Minority Health and Public Health Policy/
Institutional Review Board
Virginia Department of Health
109 Governor Street, 10th Floor East
P.O. Box 2448
Richmond, VA 23218-2448

For electronic submissions, questions or additional information, please contact:
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